DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 14, 2016

ISDIN Corp
Ms. Karen Kopicko
Regulatory Affairs Consult
100 Overlook Center, 2nd Floor
Princeton, NJ 08540

Re: K143605
Trade/Device Name: Nutraseb Facial Cream
Regulatory Class: Unclassified
Product Code: FRO
Dated: March 17, 2016
Received: March 18, 2016

Dear Ms. Kopicko:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143605

Device Name
NUTRASEB Facial Cream

Indications for Use *(Describe)*
Under the supervision of a healthcare professional, NUTRASEB Facial Cream is indicated to manage and relieve the signs and symptoms of seborrhea and seborrheic dermatitis such as itching, erythema, scaling and pain. NUTRASEB Facial Cream helps relieve dry waxy skin by maintaining a moist wound and skin environment, which is beneficial to the healing process.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

In accordance with 21 CFR 807.87(h) and 21 CFR 807.92, the 510(k) Summary for NUTRASEB Facial Cream is provided below.

Device Common Name:	Dressing, Wound
Device Proprietary Name:	NUTRASEB Facial Cream
510(k) Number:	K143605
Submitter:	ISDIN Corp. 100 Overlook Center, 2nd Floor Princeton, New Jersey 08540
Contact:	Karen L Kopicko, Regulatory Affairs ISDIN Corp. 100 Overlook Center 2nd Floor Princeton, NJ 08540 Phone: (609) 375 2142 Fax (609) 375 2001 Email: Regulatory.us@isdin.com
Alternate Contact:	Isabel Hereza, Corporate Regulatory Affairs ISDIN S.A. Provencals, 33 08019, Barcelona, Spain Phone: +34 932 40 20 Mobile: +34 690 02 69 Fax: +34 93 600 90 47 Email: Isabel.Hereza@isdin.com
Date Prepared:	April 05, 2016
Classification Regulation:	Unclassified
Panel:	General & Plastic Surgery
Product Code:	FRO
Predicate Devices:	Sinclair Skin Emulsion (currently marketed as Promiseb® Topical Cream, K050158)

Indications for Use

Under the supervision of a healthcare professional, NUTRASEB Facial Cream is indicated to manage and relieve the signs and symptoms of seborrhea and seborrheic dermatitis such as itching, erythema, scaling and pain. NUTRASEB Facial Cream helps relieve dry waxy skin by maintaining a moist wound and skin environment, which is beneficial to the healing process.

Device Description

NUTRASEB Facial Cream is a non-sterile, steroid-free, fragrance-free, water-based emulsion for the management of the signs and symptoms of seborrhea and seborrheic dermatitis which is presented for prescription use. NUTRASEB Facial cream is supplied in a polyethylene tube. Two 50 gram polyethylene tubes will be packaged together within a single carton.

Comparison of Indications for Use

NUTRASEB Facial Cream shares indications for use with the predicate device, Promiseb® Topical Cream, as both products are steroid-free, fragrance-free, water-based emulsions for the management of the signs and symptoms of seborrhea and seborrheic dermatitis. Both NUTRASEB Facial Cream and the predicate device help relieve dry, waxy skin by maintaining a moist wound environment benefiting the healing process. The proposed Indication for Use for NUTRASEB Facial Cream matches that of Sinclair Skin Emulsion (currently marketed as Promiseb® Topical Cream).

Comparison of Design and Materials

Like the referenced predicate, NUTRASEB Facial Cream contains emollients, humectants, skin conditioning agents, piroctone olamine and ascorbyl palmitate; ingredients known to be helpful in managing the signs and symptoms of seborrhea and seborrheic dermatitis. Both products are non-sterile water-based emulsions, and are applied topically to the affected skin, that upon application form a barrier that enables the skin to stay moist thus being beneficial to the healing process.

Performance Data

The following performance data are provided in support of the substantial equivalence determination.

Non-clinical Performance

Non-clinical testing was conducted to demonstrate the safety of NUTRASEB Facial Cream. Testing included in-vitro test for cytotoxicity (Agar diffusion; ISO 10993-5:2009), dermal

irritation test in rabbits and test for sensitization potential in guinea pigs (ISO 10993-5:2009). NUTRASEB Facial Cream was not cytotoxic in agar diffusion test. It was “slightly irritant” in rabbits and was mildly sensitizing in guinea pigs. The safety of NUTRASEB Facial Cream is further corroborated by a toxicological analysis of its components.

For the stability studies, the product has undergone chemical and microbiological testing as per USP<61>. The results indicate that in the closed container the product has a 36 month expiration date. Once the tube has been opened the duration of use (expiration date) is 6 months.

Clinical Performance

Several clinical tests were conducted to demonstrate the safety of NUTRASEB Facial Cream. NUTRASEB Facial Cream has been shown to have rare reports of skin sensitivity, and does not appear to induce phototoxicity or photoallergy reaction after application based on available data.

Conclusions

Identical indicated uses, similar technological characteristics and function indicate that NUTRASEB Facial Cream is substantially equivalent to the currently cleared and marketed Promiseb® Topical Cream (cleared under 510(k) K050158 as Sinclair Skin Emulsion). Biocompatibility, non-clinical and clinical evidence, supports the substantially equivalent safety of NUTRASEB Facial Cream.